UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION

MDL No. 1:13-MD-2428-DPW

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This Document Relates to:

Mervin Boyd, Individually and as Wrongful Death Beneficiary of Judith Boyd, Case No. 1:13-cv-11717-DPW;

Charles Cameron, Individually and as Wrongful Death Beneficiary of Charles Cameron, Sr., Case No. 1:13-cv-12446-DPW;

Daniel Carter, Individually and on Behalf of the Wrongful Death Beneficiaries of Anniece Carter, Case No. 1:13-cv-12459-DPW;

Joyce Marie Clark, Individually and on Behalf of the Wrongful Death Beneficiaries of Edward Lee Jenkins, Case No. 1:13-cv-12460-DPW;

Kathy Dennis as Wrongful Death Beneficiary of Ruth Ann Dennis, Case No. 1:13-cv-12467-DPW;

Geraldine Dillingham, as Next of Kin and Personal Representative of Estate of Ronnie Dillingham, Case No. 1:15-cv-12796-DPW;

Gloria Cothern Dunaway, Individually and as Wrongful Death Beneficiary of Betty Sue Cothern, Case No. 1:13-cv-11714-DPW;

Carlotta Jerry, Individually and as Next of Kin of Christopher Jerry, Case No. 1:15-cv-14121-DPW;

Alex Kazos, as Next of Kin and Personal Representative of Estate of Nick Kazos,

Case No. 1:15-cv-12376-DPW;

Janice McGhee, Individually and as Wrongful Death Beneficiary of Henry McGhee, Case No. 1:13-cv-13172-DPW;

Michael McNulty, Individually and as Wrongful Death Beneficiary of Willie Enette McNulty, Case No. 1:13-cv-12403-DPW;

Sharon Randall, as Next of Kin and Personal Representative of Estate of Winfitch Randall, Case No. 1:15-cv-12735-DPW;

Amy Riben, Wife, and Max Riben, Husband, And Their Marital Community, Case No. 1:15-cv-11134-DPW;

Kimberly Ross, Individually and on Behalf of the Wrongful Death Beneficiaries of Stella Ross, Case No. 1:13-cv-12478-DPW;

Sophia Walker, Individually and on Behalf of the Wrongful Death Beneficiaries of Hattie Myles, Case No. 1:13-cv-12487-DPW;

Beulah Williams, on Behalf of the Wrongful Death Beneficiaries of Angela Hughes, Case No. 1:13-cv-12486-DPW

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MEMORANDUM IN SUPPORT OF FMCNA'S MOTION FOR SUMMARY JUDGMENT ON THE CLAIMS OF OPT-OUT PLAINTIFFS THAT ARE BARRED BY THE LEARNED INTERMEDIARY DOCTRINE

Pursuant to Federal Rule of Civil Procedure 56, Defendants, Fresenius Medical Care Holdings, Inc., Fresenius USA, Inc., Fresenius USA Manufacturing, Inc., and Fresenius USA Marketing, Inc. (collectively "FMCNA") submit this memorandum in support of their motion for summary judgment on the claims of all opt-out plaintiffs who received their relevant dialysis treatments preceding their alleged injury: (1) at an FMCNA dialysis unit at any time; (2) at a DaVita dialysis unit after November 4, 2011; or (3) at any dialysis unit after March 29, 2012. The claims of such plaintiffs are barred by the learned intermediary doctrine because there can be no dispute that the relevant physicians were adequately warned. Sixteen of the 18 remaining opt-out cases are subject to this motion, as identified in the tables at pp. 11-13 below.[1]

I. INTRODUCTION

All the claims Plaintiffs are attempting to pursue in this litigation sound in failure to warn. Plaintiffs do not allege that FMCNA's GranuFlo® and NaturaLyte® products are inherently unsafe but, rather, that FMCNA failed to provide sufficient information to ensure they could be used safely. Under the learned intermediary doctrine, which is recognized under state law in all 16 opt-out cases at issue, the prescribing physician is the relevant audience for warnings about a medical device. For opt-out plaintiffs in at least three sets of common circumstances, the record indisputably shows the physicians were adequately warned and summary judgment should be entered in favor of FMCNA. First, physicians at FMCNA units were provided with a series of memoranda on serum bicarbonate management prepared by the

[1] As explained in FMCNA's brief in support of its motion for summary judgment regarding NaturaLyte® opt-out cases, filed on August 23, 2017 (Doc. 1907, at p. 1), FMCNA has identified multiple grounds for dispositive motions in the remaining opt-out cases. Many of the cases are subject to dismissal on more than one ground. For example, seven of the plaintiffs identified in this motion also are subject to the NaturaLyte® motion (Doc. 1906). Fourteen of the plaintiffs identified in this motion also are subject to the non-elevated bicarbonate motion (Doc. 1913). A stipulation of dismissal with prejudice was filed in the 19th opt-out case, Zachery/McClendon, on August 30, 2017. The Court dismissed the 20th opt-out case, Hearn, at the hearing on August 30, 2017.

Chief Medical Office, which contained sufficient information to allow them to use the products safely. Patients who treated at such units prior to their alleged injury thus have no failure to warn claim. Second, FMCNA's largest competitor in providing dialysis, DaVita, received the "internal memorandum" at the center of this case – the November 4, 2011 Hakim Memo – on the same day it was released to FMCNA physicians. Patients who treated at DaVita units after that date, likewise, cannot demonstrate an inadequate warning. Third, FMCNA issued an "Important Prescribing Information" notification on March 29, 2012, to all customers who use the products at issue, and Plaintiffs have admitted this notification includes the exact warning they claim FMCNA should have given. No patient who alleges an injury after March 29, 2012 has a viable claim, regardless of where they treated. For these reasons, discussed further below, FMCNA is entitled to summary judgment in the opt-out cases identified in the caption above.

II. UNDISPUTED MATERIAL FACTS

A. Communications with FMCNA Attending Physicians and Medical Directors regarding GranuFlo® and NaturaLyte®

In a number of different communications beginning in the early 2000s and continuing throughout the decade, FMCNA provided information about its acid concentrate products, acetate, acid-base balance, serum bicarbonate levels, alkalosis, the concept of "total buffer," and potential mortality and cardiac risks to physicians in its dialysis units. SOF ¶¶ 1-33; Ex. 1-8. These communications include several Chief Medical Office memoranda between 2000 and 2011 as follows:

- December 7, 2000 memorandum re: Bicarbonate Dialysate and Low Serum Bicarbonate Levels (Ex. 1)
- March 23, 2001 memorandum re: Delivered Bicarbonate and Total Buffer with Fresenius 2008H and 2008K Dialysis Machines (Ex. 2)
- April 5, 2002 memorandum re: Serum Bicarbonate Levels (Ex. 3)

- July 5, 2005 memorandum re: Bicarbonate Levels (Ex. 4)
- October 30, 2008 memorandum re: Dialysate Concentrate (Ex. 5)
- April 13, 2009 memorandum re: Dialysate Concentrate Change and Bicarbonate/Buffer (Ex. 6)
- August 27, 2009 memorandum re: Concentrate Electrolyte Lookup Program – Version 2 with Expanded Bicarbonate Range (Ex. 7)
- November 4, 2011 memorandum re: Dialysate Bicarbonate, Alkalosis and Patient Safety (Ex. 8)

In these communications, FMCNA repeatedly reminded these physicians that: (1) GranuFlo® contains 8 mEq/L of acetate and NaturaLyte® contains 4 mEq/L; (2) acetate is converted to bicarbonate in the liver; (3) too much and too little bicarbonate can pose health risks; and (4) physicians should take the acetate in GranuFlo® and NaturaLyte® into account when determining their patients' prescribed machine setting for bicarbonate to avoid both acidosis and alkalosis. SOF ¶¶ 1-33; Ex. 1-8. These Chief Medical Office memoranda were directed and sent to FMCNA medical directors and are addressed as such.

Further, any physician with privileges to attend patients at an FMCNA clinic has access to these materials. See SOF ¶¶ 34-35. FMCNA maintains an intranet site, called Doctor's Corner, where Chief Medical Office memoranda such as these and other relevant materials are posted. See SOF ¶ 34; Ex. 10. All attending physicians with privileges at FMCNA clinics and FMCNA medical directors are granted access to Doctor's Corner. See SOF ¶ 35; Ex. 9. Thus,

even if a physician was not on the original distribution list for one of the memoranda listed above, that physician would have had ready access to it on the Doctor's Corner site at any time once the physician had privileges to treat patients at an FMCNA clinic.

Plaintiffs' Second Amended Master Complaint (SAC) refers to several of FMCNA's Chief Medical Office memoranda in describing the information Plaintiffs claim physicians needed to know in order to use the products safely and admits that the information was provided to FMCNA clinics and physicians treating patients there. See SAC (Doc. 1232) ¶¶ 112, 158-162, 196-205, 208-211, 254, 256. For example, Plaintiffs cite the March 23, 2001, memo as evidence that FMCNA knew and told its medical directors that GranuFlo provides "a greater amount of acetate available to be metabolically converted to bicarbonate in the body" and physicians needed to consider "total buffer." Id., ¶¶ 159-160. Plaintiffs cite the July 5, 2005, memo as evidence of FMCNA's knowledge – which was imparted to medical directors – that "in just a few years of using GranuFlo … the mean bicarbonate for Fresenius patients had risen," "some patients are actually now alkalotic pre-dialysis," "mortality increases when the serum bicarbonate levels are >28," and physicians should consider "total buffer." Id., ¶¶ 198-199. Plaintiffs cite the April 13, 2009, memo as evidence that "Fresenius Medical Directors" were told that "there still seems to be confusion about bicarbonate settings and prescriptions for bicarbonate," and that FMCNA reminded them the bicarbonate setting on the machine does not include "the 4 mEq/L of acetate delivered by the liquid acid solution or the 8 mEq/L of acetate delivered by the GranuFlo acid powder." Id., ¶¶ 202-204. Plaintiffs acknowledge this

information was communicated to physicians at FMCNA clinics. They complain that FMCNA "did not communicate this information to non-Fresenius entities." Id., ¶¶ 162, 201, 205; see also Id., ¶¶ 254, 256.

In addition to these uniformly distributed and uniformly available Chief Medical Office memoranda, several physicians treating patients at FMCNA clinics would have received similar information through their participation in other company initiatives, such as medical advisory boards.

B. Communications with DaVita regarding GranuFlo® and NaturaLyte®

Physicians who treat patients at non-FMCNA clinics would have received or had access

to the Chief Medical Office memoranda discussed above if they also had privileges to treat patients at FMCNA clinics, as many physicians do. SOF ¶ 36.

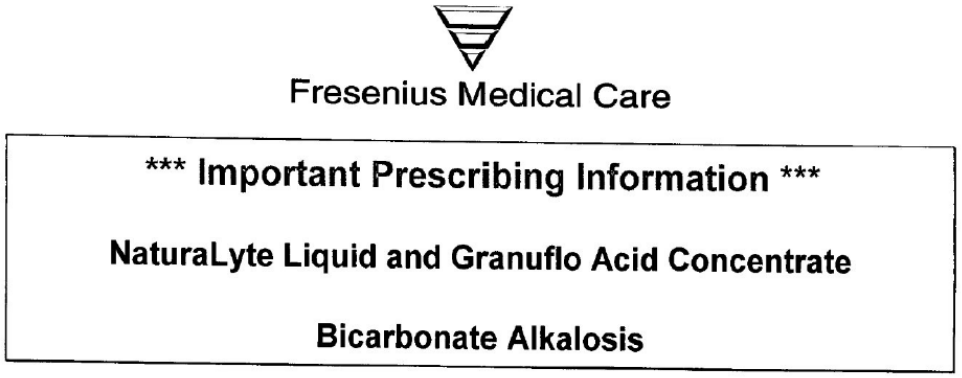
The Hakim Memo – and Plaintiffs' allegation that FMCNA did not disseminate its "findings" outside the company soon enough – is the genesis of this litigation. See SAC ¶¶ 208-211, 256. Plaintiffs allege that the Hakim Memo "tells the Fresenius medical directors that alkalosis is a significant risk factor associated with cardiopulmonary arrest" and that the "major cause of metabolic alkalosis in dialysis patients is inappropriately high dialysate total buffer concentration." Id., ¶ 209 (emphasis added). Plaintiffs emphasize Dr. Hakim's "finding[]" that "borderline elevated predialysis bicarbonate levels and overt alkalosis are significantly associated with a 6 to 8 fold greater increase of cardiopulmonary arrest and sudden cardiac death in the dialysis facility." Id., ¶ 210. Acknowledging as they must that this information was reported to physicians treating patients in FMCNA clinics, Plaintiffs complain that "Fresenius willfully and knowingly failed to adequately notify, warn and/or instruct non-Fresenius dialysis

clinics and operators … of the results of this study." Id., ¶ 211 (emphasis added); see also id., ¶ 256 (alleging that FMCNA "failed to send the Internal Memo [the Hakim Memo] warning and instructions to competitor dialysis clinics that used Defendants' products and dialysis machines"), ¶¶ 222-223 (recounting criticisms of FMCNA for not warning "all users of the product" of the risks identified by Dr. Hakim).

C. The March 29, 2012 Important Prescribing Information

On March 29, 2012, working with the FDA, Fresenius issued to all users of GranuFlo®

and NaturaLyte® a document that was intended to warn all customers of the conclusions Dr. Hakim had reached as follows:



Fresenius Medical Care

***** Important Prescribing Information *****

NaturaLyte Liquid and Granuflo Acid Concentrate

Bicarbonate Alkalosis

DATE: **March 29, 2012**

SUBJECT: **Risk of Alkalosis with acetate containing dialysis acid concentrates**

SOF ¶¶ 44-48; Ex. 14. This "Important Prescribing Information" discussed the acetate contents of the products, "total buffer," and risk factors for cardiopulmonary arrest. Id. It also stated:

> NaturaLyte Liquid contributes 4.0 mEq/L of acetate and Granuflo contributes 8.0 mEq/L of acetate to the final dialysate; which in addition to bicarbonate, combine to the total buffer that the patient receives from the dialysate. Acetate is also contained in the dialysis acid concentrates produced by other manufacturers. Since acetate is rapidly converted into bicarbonate by the liver, the bicarbonate prescription entered into the dialysis machine underestimates the total buffer that the patient receives from the dialysate by ~8 mEq/L with dialysate prepared from Granuflo (powder) or by ~4 mEq/L with dialysate prepared from NaturaLyte (liquid).

SOF ¶ 46. The notification advised physicians to individualize prescriptions and "review[] them monthly with consideration of patient's pre-dialysis bicarbonate and dialysate total buffer." SOF ¶ 48.

FMCNA sent the March 29, 2012 notification to all known customers that had purchased GranuFlo® or NaturaLyte®, whether it was a dialysis unit operated by FMCNA, DaVita, or

anyone else.[2] SOF ¶ 44. Plaintiffs' SAC acknowledges that FMCNA distributed the March 29, 2012, notification to clinics, and that it contained the information set forth above. SAC ¶¶ 214-216. Plaintiffs specifically allege that this document included the warning, "[a] major cause of metabolic alkalosis in dialysis patients is inappropriately high dialysate total buffer concentration." Id., ¶ 215. Significantly, Plaintiffs' original Master Complaint limited their claims to injuries that occurred before the "Important Prescribing Information" was issued, pleading that "Fresenius failed to properly warn of the dangers associated with the use of its products **up to March 29, 2012**." Master Complaint ¶ 205 (Doc. 471-1) (emphasis added).[3]

Further, during these MDL proceedings, Plaintiffs' counsel has admitted that the March 29, 2012, notification contains the precise warning they claim FMCNA was required to give about GranuFlo® and NaturaLyte®. At the pre-trial conference in Dial, Plaintiff's counsel confirmed that the March 2012 notification is the key document containing the information he claims doctors needed to know about the products, describing it as follows:

> **[I]t contains the essential causation**, the link between alkalosis and the potassium, and it's an official notification where they're sending this out…. **[I]t's information that if [a treating physician] had gotten earlier he might have changed what he did.** But **it's the essential causation story**. It's saying that the alkalosis has these effects….

SOF ¶ 49; Ex. 16.

Notably, reiterating the same information in FMCNA's March 29, 2012, notification, on May 25, 2012, FDA issued a "Safety Communication" entitled "Dialysate Concentrates and Alkali Dosing Errors with Hemodialysis," which was posted on the FDA website. SOF ¶ 51; Ex.

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[3] Even in the SAC, Plaintiffs specifically limit their failure to warn claim after March 29, 2012 to non-FMCNA clinics. SAC ¶ 257 ("Even after the Internal Memo was leaked to the FDA and Fresenius sent some information to non-Fresenius clinics on or about March 29, 2012, that disclosure did not contain all of the information that was known to Fresenius and necessary to warn and protect patients.").

18. That communication reiterated that "acetic acid and acetate" are "potential sources of alkali [that] can contribute to elevated bicarbonate levels in patients undergoing hemodialysis." Id. It continued, "This can contribute to metabolic alkalosis, which is a significant risk factor associated with cardiopulmonary arrest, low blood pressure, hypokalemia, hypoxemia, hypercapnia, and cardiac arrhythmia." Id.

D. Other Sources of Information and Knowledge

In addition to all the disclosures discussed above, nephrologists who have testified in this litigation, including some of Plaintiffs' own experts, have confirmed that members of their field generally are independently aware of much of the same information that Plaintiffs claim FMCNA was required to provide. For example, Dr. David Goldfarb, one of Plaintiffs' nephrology experts, testified that nephrology fellows know from medical school that acetate metabolizes into bicarbonate in the liver. SOF ¶ 52. Dr. Derek Fine, another of Plaintiffs' nephrology experts, testified that, before he ever was hired as an expert in this litigation, he knew about acetate and was teaching his nephrology fellows about acetate, how it can be metabolized to bicarbonate in the body, and to "look at the acetate" if a patient becomes alkalotic. SOF ¶ 53. Likewise Dr. Paul Miller, who instigated the 2012 labeling recall and litigation against Fresenius regarding GranuFlo®, agreed that "most nephrologists who have been through high school and

then college and then medical school, would understand that acetate converts in the body to bicarbonate." SOF ¶ 54.

Witnesses who are not affiliated with FMCNA also have confirmed that, for every acid concentrate in use in a dialysis clinic, including GranuFlo® and NaturaLyte®, physicians have ready access to product labels that identify their acetate contents and other constituents. SOF ¶¶ 55, 56, 57, 60. In addition, in clinics where FMCNA dialysis machines are used, physicians also have access to screens that again show the amount of acetate in the dialysate and the bicarbonate setting, among other information, making it clear which product is being used with each patient and what bicarbonate level was prescribed. SOF ¶¶ 58, 59.

E. Opt-Out Plaintiffs Subject to This Motion

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III. LEGAL STANDARD FOR SUMMARY JUDGMENT

"Summary judgment is appropriate when 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.'" Pagano v. Frank, 983 F.2d 343, 347 (1st Cir. 1993) (quoting Fed. R. Civ. P. 56(c)). When a defendant moves for summary judgment based on a lack of evidence supporting the plaintiffs' claim, "the plaintiff must establish the existence of a triable issue which is both genuine and material to his claim." Id. Plaintiffs "must present definite, competent evidence to

rebut the motion" and cannot merely rest on "conclusory allegations, improbable inferences, and unsupported speculation." Id. If the plaintiffs' theory of liability is unsupported, summary judgment should be entered in favor of the defendant. See, e.g., Geshke v. Crocs, 740 F.3d 74, 77 (1st Cir. 2014); see also Koken v. Black & Veatch Constr., 426 F.3d 39, 49 (1st Cir. 2005) ("When there is so little evidence tending to show a critical element of a plaintiff's claim that the jury would have to speculate in order to return a verdict for the plaintiff, a defendant is entitled to summary judgment.").

IV. ARGUMENT

The learned intermediary doctrine is widely recognized in "the vast majority of jurisdictions" across the United States. See In re Norplant Contraceptive Prods. Liab. Litig., 215 F. Supp. 2d 795, 804 (E.D. Tex. 2002). It provides that a manufacturer's duty to warn of dangers inherent in a prescription drug or medical device runs to the prescribing physician, not to the patient. Id. at 803, 806. Under any substantive state law potentially applicable in the opt-out cases that are subject to this motion, the learned intermediary doctrine is available. See, e.g., Bock v. Novartis, 661 F. App'x 227, 232 (3d Cir. 2016) (under Pennsylvania law, manufacturer must "exercise reasonable care to inform a physician"); Smith v. Johnson & Johnson, 483 F. App'x 909, 913-15 (5th Cir. 2012) (under Mississippi law, "manufacturer's duty to warn runs only to the prescribing physician"); Tortorelli v. Mercy Health, 2010 OK CIV APP 105, ¶ 27, 242 P.3d 549, 558-60 (doctrine "shields a manufacturer from liability if it has adequately warned a prescribing physician"); Calhoun v. Hoffman-La Roche, 768 So. 2d 57, 61-62 (La. Ct. App. 2000) (manufacturer "has fulfilled its obligation when it has informed the prescribing and treating physicians of the risks of harm"); Felix v. Hoffmann-LaRoche, 540 So. 2d 102, 104-05 (Fla. 1989) (manufacturer must adequately warn "the prescribing physician"); Huck v. Wyeth, 850 N.W.2d 353, 360 (Iowa 2014) (recognizing under the doctrine, duty to warn would run to

the "physician," not the patient).

When the learned intermediary doctrine applies, a plaintiff must prove the following to recover for failure to warn: (1) that the product warnings given by the manufacturer were inadequate; and (2) that the inadequate warnings caused the plaintiff's alleged subsequent injuries. In re Norplant, 215 F. Supp. 2d at 803-04. If the relevant physician received the warning that the plaintiff claims should have been given or otherwise was adequately warned, the duty to warn has not been breached and no failure-to-warn claim lies.

Plaintiffs' allegations make clear that, no matter how their claims are captioned, the gravamen of the complaint is failure to warn. The underlying grievance that pervades the SAC is the claim that FMCNA failed to issue sufficient warnings that, according to the theory of total buffer, using GranuFlo® and NaturaLyte® allegedly would cause patients to have "excessive" serum bicarbonate levels, which Plaintiffs claim leads to alkalosis and cardiac arrest. See, e.g., SAC ¶¶ 1-3, 110, 113, 126-127, 158, 168-169, 177, 182, 211, 217-218, 227-229. Thus, the learned intermediary doctrine is a complete bar to all claims in any opt-out case where FMCNA provided adequate warnings.[6]

[6] Although Plaintiffs make cursory references to alleged "negligent design" issues or "design defects," those allegations all incorporate and are founded on the grievance that FMCNA failed to provide adequate warnings about the two products at issue. See SAC ¶ 110 (alleging that, when GranuFlo is used, "the patient is exposed to an unanticipated amount of bicarbonate and consequently an unanticipated amount of total buffer that exceeds what was prescribed by the physician"), ¶ 194 (alleging that machine design changes would have "ensure[d] that the amount of bicarbonate delivered to the patient was the amount prescribed by their physicians, especially when NaturaLyte and/or GranuFlo were used"), ¶ 293 ("negligent design" count of the SAC alleging that Fresenius had "knowledge of the safety problems" with GranuFlo and "suppressed this knowledge from the general public"). A plaintiff cannot "plead around the learned intermediary doctrine" by alleging "defective design" and breach of warranty claims that are "disguised failure-to-warn, fraud-by-omission claims." Gonzalez v. Bayer, 930 F. Supp. 2d 808, 820 (S.D. Tex. 2013).

A. Plaintiffs Asserting Claims Involving Patients Who Treated at FMCNA Units Have No Claim Because Their Physicians Were Adequately Warned.

In a series of Chief Medical Office memoranda spanning over the course of more than a decade, FMCNA uniformly provided information about GranuFlo® and NaturaLyte®, acid/base balance issues, serum bicarbonate levels, and potential mortality and cardiac risks to FMCNA physicians. See SOF ¶¶ 1-33; Ex.1-8. All of these memoranda were addressed and distributed directly to FMCNA medical directors. See id. Further, for each opt-out case where the patient was treating at an FMCNA unit prior to the alleged injury, FMCNA records show that the relevant nephrologists had access to the Doctor's Corner site where these (and other) materials were available at any time. SOF ¶¶ 34-36,

There can be no dispute that the physicians who prescribed dialysis for these patients received these communications.

The SAC likewise acknowledges that FMCNA imparted its knowledge to physicians treating at its own clinics, and Plaintiffs' complaint is about disclosures to doctors in other facilities. The SAC is replete with allegations about information that FMCNA "told Fresenius medical directors," "informed Defendants' medical directors," or "communicated to the Defendants' medical directors." See SAC ¶¶ 159-161 (March 2001 memo), ¶¶ 197-200 (July 2005 memo); ¶¶ 203-204 (April 2009 memo), ¶¶ 209-210 (November 2011 memo). The SAC acknowledges that these communications provided the essential information Plaintiffs claim was required to make an adequate warning: how much acetate was "delivered" by GranuFlo® and NaturaLyte®; that this acetate is metabolized and converted into bicarbonate; the view that this increase in "total buffer" would increase the patients' serum bicarbonate; and potential dangers

of high bicarbonate levels and post-dialysis alkalosis. SAC ¶¶ 254, 256. The SAC also makes clear that Plaintiffs' complaint is that the same information was not disseminated more widely to "non-Fresenius entities." See SAC ¶¶ 162, 201, 205, 211; see also id., ¶¶ 254, 256.

In addition, the information these physicians received in FMCNA communications was supplemented by information contained on the product labels and machine screens in the clinics, as well as their own education. The product labels for GranuFlo® and NaturaLyte® both identify their acetate contents. SOF ¶¶ 55-57, 60. The display screens on FMCNA dialysis machines show the bicarbonate setting prescribed for the patient and the acetate contents of the acid concentrate that is being used in the treatment. SOF ¶¶ 58, 59. And testimony from Plaintiffs' own experts demonstrates that any nephrologist should understand from his or her schooling that acetate converts to bicarbonate in the human body. SOF ¶¶ 52, 53.

The same information was reinforced through other channels, as well, demonstrating that FMCNA physicians were adequately warned not just once, but repeatedly.

In sum, based on communications from the Chief Medical Office, coupled with the labels and machine screens in the clinic and their own nephrology education, attending physicians and medical directors at FMCNA clinics were aware of all the information they needed to prescribe GranuFlo® and NaturaLyte® safely and effectively. This includes knowledge that: (1) the relevant product was being used in their patient's dialysis treatments; (2) dialysate solution made

with GranuFlo® has 8 mEq/L of acetate and dialysate solution made with NaturaLyte® has 4 mEq/L; (3) acetate diffuses from the dialysate solution into the patient's blood during dialysis; (4) acetate converts to bicarbonate in the liver; (5) the doctor needed to take this into account when prescribing the machine setting for bicarbonate for the patient's dialysis treatments, because the machine does not do so automatically; and (6) there potentially were increased risks for certain patients with high (and low) serum bicarbonate levels. Because medical directors and attending physicians at FMCNA clinics received adequate warnings, no failure-to-warn claim can lie in any opt-out case involving a patient whose last dialysis treatment prior to the alleged injury occurred in an FMCNA clinic.

B. Plaintiffs Asserting Claims Involving Patients Who Treated at DaVita Units After November 4, 2011 Also Have No Claim Because DaVita Received the Hakim Memo.

. Thus, as to those patients, there can be no dispute that an adequate warning was given.

The centerpiece of Plaintiffs' failure-to-warn theory in this litigation is that FMCNA "willfully and knowingly failed to adequately notify, warn and/or instruct non-Fresenius dialysis clinics and operators" of the results of Dr. Hakim's review of in-center cardiopulmonary arrest data and his findings that those events were related to patients' serum bicarbonate levels. SAC ¶ 211.

. Plaintiffs do not allege that FMCNA was required to give any different or additional warning besides the Hakim Memo as of November 4, 2011. When DaVita had that same

information on that date, FMCNA cannot be liable for failure to warn as to any DaVita patient whose alleged injury occurred afterwards.

Underscoring the adequacy of the warnings given in these cases, at least three of the physicians involved had access to FMCNA's Doctor's Corner site where all of its Chief Medical Office memoranda, including the Hakim Memo, were posted.

The learned intermediary doctrine applies and bars Plaintiffs' claims in these cases.

C. Plaintiffs Asserting Claims Involving Injuries After March 29, 2012 Have No Claim Because The Physicians Received the Exact Warning Plaintiffs Claim FMCNA Was Required to Give.

Finally, the learned intermediary doctrine bars the claims of all opt-out plaintiffs alleging injuries after March 29, 2012, because FMCNA indisputably complied with its alleged duty to warn physicians treating patients at any facility using the products by that date. Plaintiff's counsel has admitted the March 2012 "Important Prescribing Information" contains the "essential" information physicians needed to make an informed prescribing decision. SOF ¶ 49; Ex. 16. The original Master Complaint did not even attempt to assert any claims for that post-March 29, 2012 time period. Doc. 471-1, ¶ 205. Although Plaintiffs subsequently amended their pleading, these factual assertions "still remain[] as … statement[s] once seriously made by

an authorized agent, and as such [are] competent evidence of the facts stated …." Global ePoint v. GTECH, 58 F. Supp. 3d 178, 190 (D.R.I. 2014).

When as here a physician received the exact warning that Plaintiffs say FMCNA should have provided, no failure to warn claim lies.

For all these reasons, FMCNA respectfully requests that the Court enter summary judgment in its favor in the opt-out cases identified above.

Dated: September 8, 2017

Respectfully submitted,

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CERTIFICATION OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served on Plaintiffs' counsel by e-mail on September 8, 2017, to:

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